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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATT	ORNEY DOCKET NO.
09/529,	319 02/	09/00	POULIN		R	ILEX:040/019
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			HM22/0628	, .		
STEVEN L HIGHLANDER				_	KUMAR,S	
FULBRIG	HT & JAWO	RSKI			ART UNIT	PAPER NUMBER
SUITE 2	400			_		

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

1621

DATE MAILED:

# Application No.

09/529,319

Applicant(s)

Poulin et al

Office .	Action	Summary
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Examiner

r Art Unit Shailendra Kumar 1621

	The MAILING DATE of this communication appears	on the cover sheet with the corres	
A SH THE N - Exter af - If the be - If NO co - Failur - Any r	for Reply ORTENED STATUTORY PERIOD FOR REPLY IS SET MAILING DATE OF THIS COMMUNICATION. Insigns of time may be available under the provisions of 37 Ceter SIX (6) MONTHS from the mailing date of this communication period for reply specified above is less than thirty (30) days a considered timely. In period for reply is specified above, the maximum statutory immunication. The to reply within the set or extended period for reply will, by reply received by the Office later than three months after the reply attent term adjustment. See 37 CFR 1.704(b).	EFR 1.136 (a). In no event, however, cation.  s, a reply within the statutory minimur  period will apply and will expire SIX (compared to be compared to be	may a reply be timely filed  n of thirty (30) days will  6) MONTHS from the mailing date of this  come ABANDONED (35 U.S.C. § 133).
Status 1) 💢	Responsive to communication(s) filed on Feb 9, 20	000	·
2a) 🗌	This action is <b>FINAL</b> . 2b) 💢 This ac	tion is non-final.	
3)□	Since this application is in condition for allowance closed in accordance with the practice under Ex pa		
Disposi	tion of Claims		
4) 💢	Claim(s) <u>1-43</u>	is/arc	e pending in the application.
4	la) Of the above, claim(s)	is/ar	e withdrawn from consideration.
5) 🗆	Claim(s)		is/are allowed.
6) 💢	Claim(s) <u>1-43</u>		is/are rejected.
7) 🗆	Claim(s)		is/are objected to.
8) 🗆	Claims	are subject to restric	ction and/or election requirement.
9) ☐ 10) ☒ 11) ☐	tion Papers  The specification is objected to by the Examiner.  The drawing(s) filed on is/are  The proposed drawing correction filed on  The oath or declaration is objected to by the Exam	is: a)□ approved	b}□ disapproved.
13)⊡ a) ⊑	under 35 U.S.C. § 119  Acknowledgement is made of a claim for foreign particle. All b) Some* c) None of:  1. Certified copies of the priority documents have compared to the priority of the priority	ve been received.  ve been received in Application Notes to the documents have been received in the law (PCT Rule 17.2(a)).  ne certified copies not received.	No In this National Stage
Attachm	entis)		
	otice of References Cited (PTO-892)	18) Interview Summary (PTO-413) Paper	No(s)
	otice of Draftsperson's Patent Drawing Review (PTO-948)	19) Notice of Informal Petent Application	(PTO-152)
17) 🔲 In	formation Disclosure Statement(s) (PTO-1449) Paper No(s).	20) Other:	

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#### **DETAILED ACTION**

Claims 1-43 are pending in this application.

1. Receipt-is-acknowledged of papers submitted under 35-U-S-C-1-19(a)-(d), which papers have been placed of record-in the file.

# Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims read as "wherein carbon atom of said original polyamine comprises an amide group, and the carbon is located between two internal nitrogen atoms", it is not clear as to which carbon atom is being referred to, because in an a polyamine there are various carbon atoms between various nitrogen atoms, and further, claim 3, reads "dimer of said original polyamine, the monomer of said dimer being linked together by a spacer side chain, anchored to the amido group of each monomer", again, the chemistry should be clear as to what is being claimed, the

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description, is so unclear as to come to any conclusion of what is being claimed. Thus claims are rendered indefinite.

Claims 16-20 provides for the use of synthetic derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPO 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPO 475 (D.D.C. 1966).

#### Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-12, 15, 22-26, 28-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al, J. Biol. Chem. 1996).

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Huber et al, in the title reads on the same compound as claimed herein, thus anticipating the claims.

# Claim Rejections - 35 U.S.C. § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deer Co.*, 383 U.S. 1, 148 USPO 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-15 and 21-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al.

Huber et al teach structurally similar compounds as claimed herein. Note, the title of the reference.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds within the structure of the reference, because they are structurally so similar to those claimed herein, with the reasonable expectation of achieving a successful pharmaceutical composition, absent evidence to the contrary.

### **Double Patenting**

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPO 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPO 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 13-15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13-15 of prior U.S. Patent No. 6,083,496. This is a double patenting rejection.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPO 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPO 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPO 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

13. Claims 1-12, and 21-43 are rejected under the judicially created doctrine of double patenting over claims 1-16 of U. S. Patent No. 6,083,496 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the generic structure of the instant claims extensively overlap those of the above patent, as evidenced by compounds of claims 13-15.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPO 210 (CCPA 1968). See also MEP. § 804.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to S.Kumar whose telephone number is (703) 308-4519. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S.Kumar

6/28/01

SHAILENDRA KUMAR PRIMARY EXAMINER GROUP 1298 )607